Exhibit A

In Re National Prescription Opiate Litigation **(MDL No. 2804)**

SUMMARY SHEET OF ISSUES RAISED

Manufacturer Defendants' Motion For Summary Judgment That Plaintiffs' State-Law Claims Are Preempted And Their Federal Claims Are Precluded (filed June 28, 2019)

A. Preemption/Preclusion of Marketing Claims

Issue 1: Do Plaintiffs challenge the Manufacturers' labeling of their opioid medications?

Answer to Issue 1: Yes. The term "labeling" broadly encompasses "representations made in marketing materials." *See Muscogee* R. & R. at 30, ECF No. 1499, *adopted by* Op. and Order at 2, ECF No. 1680; *see also* 21 U.S.C. § 321; *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013). And Plaintiffs *do* seek to hold the Manufacturers liable for marketing their medications for the treatment of chronic, non-cancer pain and for failing to issue dose and duration limitations. *See, e.g.*, Ex. 2 (Report of David T. Courtwright, Ph.D.) at 54[1]; Ex. 10 (Plaintiffs' Nov. 2, 2018 Amended Responses to First Set of Interrogatories) at 6.

Issue 2: Are Plaintiffs' state-law claims preempted to the extent they assert that the Manufacturers should not have marketed their opioid medications for chronic, non-cancer pain and/or that dose and duration limitations should have been set?

Answer to Issue 2: Yes. The FDA has approved opioid medications for the treatment of chronic pain without additional dose or duration limitations, preempting Plaintiffs' theory that the Manufacturers should not have sold their medications for that purpose. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488 (2013). Further, federal law preempts state-law claims where there is "'clear evidence' that the FDA would not have approved the warning that state law requires." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019) (citing *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)). This question is "a legal one for the judge, not a jury" (*id.* at 1679), and such "clear evidence" exists here. *First*, in 2013, after careful consideration, the FDA rejected requests to label opioid medications as unsafe for the treatment of chronic, non-cancer pain and to impose maximum dose and duration requirements. *See* Ex. 12 (Sept. 10, 2013 Letter from FDA to PROP) at 5, 6 & n.30, 8, 11-17. On the basis of this "clear evidence," a North Dakota court recently found that all of the State of North Dakota's claims against Purdue were preempted. Ex. 16 (Order Granting Defs.' Motion to Dismiss) at ¶¶ 16, 28-31. In addition, in May 2019, the FDA again stated that opioid medications "provide clinically significant analgesic benefit, including for pain for which other analgesics are inadequate." *See* Ex. 1 (May 2019 FDA Memorandum) at 9. The FDA also concluded that "most analgesics have no maximum dose" and that "over time some patients may require increases in their dose." *Id.* at 10. An FDA task force also "*did not recommend* any absolute limits on the individual dose or total daily dose of opioid analgesics." *Id.* at 12. Given this clear evidence, Plaintiffs' state-law claims are preempted to the extent they claim the Manufacturers mis-marketed opioid medications with respect to use for chronic, non-cancer pain; dosage; or duration of use.

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[1] All exhibits referenced herein are exhibits to the Declaration of Jonathan L. Stern in Support of Manufacturer Defendants' Motion for Summary Judgment that Plaintiffs' State-Law Claims Are Preempted and Their Federal Claims Are Precluded.

Issue 3: Are Plaintiffs' RICO claims precluded to the extent they assert that the Manufacturers should not have marketed their opioid medications for chronic, non-cancer pain and/or that dose and duration limitations should have been set?

Answer to Issue 3: Yes. One federal statute precludes the application of another when the two statutes conflict with, rather than complement, one another. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 115 (2014). Because Plaintiffs seek to impose liability under RICO for failure to make certain warnings that the FDA expressly rejected under the Food, Drug, and Cosmetic Act ("FDCA"), Plaintiffs' RICO claims place RICO in conflict with the FDCA and thus are precluded.

B. Preemption/Preclusion of Fraud-On-The-DEA Claims

Issue 4: Do Plaintiffs premise their claims on a theory that the Manufacturers committed fraud upon the Drug Enforcement Administration ("DEA")?

Answer to Issue 4: Yes. Plaintiffs claim that the Manufacturers misled the DEA in order to "fraudulently increas[e] the quotas" set by the DEA for permissible sales of opioids. *See*, *e.g.*, Ex. 14 (Pls.' Dec. 28, 2018 Suppl. Objs. And Resp. to Mfr Defs.' Interrogatory Nos. 28/29) at ¶¶ 4, 7, 30; *see also id.* at ¶¶ 32, 34.

Issue 5: Are Plaintiffs' state-law claims preempted to the extent they are premised on a theory that the Manufacturers were able to sell excess opioids by misleading the DEA?

Answer to Issue 5: Yes. State-law claims that rest upon fraud on a federal agency are preempted. *See Buckman Company v. Plaintiffs' Legal Cmte.*, 531 U.S. 341 (2001). State and federal law conflict here because the federal Controlled Substances Act "empowers the [DEA] to punish and deter fraud against the [DEA]," charges the DEA with "the difficult task of regulating the . . . distribution" of controlled substances, and requires the DEA to strike a "somewhat delicate balance" between the need to ensure access to beneficial medications and the need to deter abuse. *See id.* at 348, 350; *see also* 21 U.S.C. 801 *et seq.* This balance would "be skewed by allowing state-law fraud-on-the-[DEA] claims." *See Buckman*, 531 U.S. at 341. Plaintiffs' state-law claims would also "dramatically increase the burdens" facing the Manufacturers and incentivize the Manufacturers "to submit a deluge of information" that the DEA "neither wants nor needs." *See id.* at 350-51. In sum, Plaintiffs' "[s]tate-law fraud-on-the-[DEA] claims inevitably conflict with the [DEA's] responsibility to police fraud consistently with the [DEA's] judgment and objectives." *See id.* at 350.

Issue 6: Are Plaintiffs' federal RICO claims precluded to the extent they are premised on a theory that the Manufacturers were able to sell excess opioids by misleading the DEA?

Answer to Issue 6: Yes. *Buckman* has been applied to preclude federal statutory claims. *See*, *e.g.*, *United States ex rel v. Medtronic, Inc.*, LACV1501212JAKASX, 2017 WL 4023092, at *7 (C.D. Cal. Sept. 11, 2017) (*Buckman* applied to prevent a fraud-on-the-FDA claim under the federal False Claims Act). Plaintiffs' federal RICO claims are thus precluded for the same reasons that the state-law claims are preempted. *See* Answer to Issue 5 *supra*.